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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,323	05/18/2005	Maria Petrou	05-405	5681

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EXAMINER	
AZARIAN, SEYED H	

ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,323	PETROU ET AL.	
	Examiner	Art Unit	
	Seyed Azarian	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,12-14,17,18,21-23,26 and 27* is/are rejected.

7)☒ Claim(s) *4,5,8-11,15,16,19,20,24,25,28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows;

Claim 21 states, "Computer software for use in histological assessment". Such claimed "computer software" do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer. In order to be statutory the claim should state, "A computer readable medium storing a computer application program read by a computer system; or a computer readable medium encoded with one of the following: a "computer program"; "software"; "computer executable instructions"; or instructions capable of being executed by a computer"; or state, "A computer readable medium "storing a" computer program; or state, "A computer readable medium "embodied with a" computer application program read by a computer system".

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 6-7, 12-14, 17-18, 21-23 and 26-27, are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabib et al (U.S. patent 5,991,028) in view of Lee al (U.S. patent 5,978,497).

Regarding claim 1, Gabib discloses a method of histological assessment of nuclear pleomorphism by identifying image regions potentially corresponding to cell nuclei in histological image data (column 27, lines 29-37, histological types of intraductal carcinoma have been recognized: comedo, cribriform, micropapillary and solid. All are recognized and classified by specific criteria and subdivided primarily by architectural pattern, “cellular pleomorphism” and nuclear hyperchromasia [Page D L, Anderson T G (1987). Diagnostic histopathology of the breast);

determining perimeters and areas of identified image regions, calculating image region shape factors from the perimeters and areas and assessing pleomorphism from the shape factors’ statistical parameters (column 29, lines 37-50, with reference now to FIGS. 7a-h and 8 a-h. As was determined by the classification map algorithm, the area covered by each of the six classified spectral regions which appeared in the nucleus of each of the cells exemplified in FIGS. 5a-h and thirteen additional cells of a known histological classification was determined, and the averaged areas categorized by numbers from 1-6 in accordance with the numerical references of the reference spectra shown in FIG. 6 and listed in Table 2 are presented histographically in the abundance histogram s in FIGS. 7a-h).

However Gabib discloses (column 33, lines 29-36, FIGS. 14a-h classified images of the cells described under Example 2 above, the classifying network had the option of defining a 'none classified' pixel. Its definition depends on the user through a "threshold" decision. In the images of FIGS. 13a-h). But does not explicitly state its corresponding "the method including thresholding the image data to render it binary". On the other hand Lee in the same field of identification of cells teaches (column 9, lines 33-45, the threshold image is combined with two predetermined offset values to generate three threshold images. The first offset is subtracted from each gray scale pixel value of the original threshold image 33 to create a low threshold image. The second offset value is added to each gray scale pixel value of the threshold image to create a high threshold image. Each of these images--medium threshold, which is the original threshold images, low threshold, and high threshold—are separately combined with the enhanced image to provide three binary threshold images: a low threshold binary image 35; a medium threshold binary image 37; and a high threshold binary image 39).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Gabib invention according to the teaching of Lee because it provides technique to identifies objects of interest and creates a threshold image, which applied to the enhanced images that can easily be implemented in an imaging device.

Regarding claim 2, Gabib discloses a method according to claim 1 wherein the shape factors' statistical parameters comprise at least one of their mean, weighted mean, median, mode, maximum and minimum (column 17, lines 33-43, in Equation 6, is

a general weighting response function that provides maximum flexibility in computing a variety of gray scale images, all based on the integration of an appropriately weighting spectral image over some spectral range. For example, by evaluating Equation 6 with three different weighting functions, corresponding to the tristimulus response functions for red (R), green (G) and blue (B), respectively, it is possible to display a conventional RGB color image).

Regarding claim 7, Gabib discloses a method according to claim 6 wherein the step of transforming colour image data into grayscale image data is carried out by Principal Component Analysis (PCA) in which the grayscale image data is a first principal component (column 20, lines 45-53, decorrelation statistical analysis is directed at extracting decorrelated data out of a greater amount of data, and average over the correlated portions thereof. There are a number of related statistical decor relation methods. Examples include but not limited to principal component analysis (PCA), canonical variable analysis and singular value decomposition, etc., of these methods PCA is perhaps the more common one, and is used according to the present invention for decorrelation of spectral data).

Regarding claim 21, Gabib discloses computer software for use in histological assessment of nuclear pleomorphism and having instructions for controlling a computer to identify image regions potentially corresponding to cell nuclei in histological image data, the software also having instructions for controlling a computer to threshold the image data to render it binary, determine perimeters and areas of identified image regions, calculating image region shape factors from the perimeters and areas and

assess pleomorphism from the shape factors' statistical parameters (see claim 1, also column 32, lines 28-45, refer to computer software).

With regard to claims 3, 6 and 12-14 the arguments analogous to those presented above for claims 1, 2, 7 are respectively applicable to claims 3, 6 and 12-14.

With regard to claims 17-18, 22-23 and 26-27 the arguments analogous to those presented above for claims 1, 2, 7 and 21 are respectively applicable to claims 17-18, 22-23 and 26-27.

Allowable Subject Matter

4. Claims 4, 5, 8-11, 15-16, 19, 20, 24-25 and 28-29 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Information

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.
Status information about the PAIR system, see http:// pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Seyed Azarian/
Primary Examiner, Art Unit 2624
March 29, 2008